

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESAL PRICE  
LITIGATION

MDL NO. 1456

CIVIL ACTION: 01-CV-12257-PBS

THIS DOCUMENT RELATES TO:  
ALL ACTIONS

Hon. Patti B. Saris

**TRACK 2 DEFENDANTS' JOINT MEMORANDUM REGARDING  
THE COURT'S INTENTION TO RENDER A LEGAL  
DEFINITION OF THE TERM "AVERAGE WHOLESAL PRICE"**

At the May 23, 2006 hearing, the Court expressed an intention, at the urging of plaintiffs and the Track 1 Defendants, "to define AWP as a matter of law" in the context of deciding summary judgment motions filed in the Track 1 cases. Tr. at 28.<sup>1</sup> Specifically, the Court suggested, and counsel for the Track 1 Defendants agreed, that it was necessary for the Court to construe the meaning of the term AWP as it appears in the Medicare statutes and regulations. Tr. at 8.<sup>2</sup> The Track 2 Defendants respectfully disagree that it is necessary or appropriate for the Court to construe the meaning of the term "AWP" in the Medicare statutes or regulations, or to establish the "meaning of AWP" as a matter of law based on its interpretation of Congressional intent.

The Court's decision on this issue is of great interest and importance to all defendants (and all cases in the MDL), including the Track 2 Defendants. It is difficult to see how the Court could take a fresh look at this issue at a later point when the interests of the Track 2 Defendants are directly at stake. The Track 1/Track 2 distinction is not serving a useful purpose in this instance and in fact is denying the Track 2 Defendants their right to be heard before their interests are adjudicated. The Track 2 Defendants believe it would be most efficient for the Court and protective of the their rights for them to be heard on this issue at this stage.

<sup>1</sup> "THE COURT: . . . All right, I do think it's appropriate for me, and I think both sides are urging me to do that, to define AWP as a matter of law."

<sup>2</sup> "THE COURT: So it's put into a statute, and I have to construe the statute.  
MR. MONTGOMERY: Correct."

Plaintiffs' claims are brought under various consumer protection statutes under a theory that defendants' pricing practices deceived the government, private payors and individuals. Plaintiffs do not allege that any of the defendants directly or even vicariously violated the Medicare statute or regulations implementing that statute. Nor do Plaintiffs allege that the provisions of the Medicare statute at issue, during the relevant time frame, regulated the conduct of drug manufacturers.

The question before the Court on motions for summary judgment is whether the evidence raises sufficient issues of material fact to warrant placing the state consumer protection claims of deception before a jury as to each individual defendant. The Court must consider whether the evidence is sufficient to allow a jury to decide, among other things, whether (a) each defendant engaged in deceptive conduct within the meaning of the relevant consumer protection statutes, (b) the allegedly injured parties reasonably relied on that conduct (where this element applies), and (c) the alleged deceptive conduct was the legal cause of the claimed injuries. This requires inquiry into the evidence on such matters as the defendants' price reporting practices (if any), the government's and plaintiffs' contemporaneous understandings regarding the meaning of the published AWP, and the intentions of the government and other relevant payors at the time in basing reimbursement on the published AWP. It does not require the Court to decide the meaning of AWP as a matter of law through statutory construction of the term as used in the Medicare statute.

Indeed, defining AWP by the plain meaning of the words "average," "wholesale" and "price," in the absence of evidence it was so understood by the parties at the time, would be error in the context of this case and these motions. The record before the Court makes it absolutely clear that reimbursing authorities used AWP in order to give providers a margin or spread that would be part of the reimbursement amount needed to guarantee access. A statutory interpretation rendered by any Court in 2006 – at odds with the usage of the term by the industry at the time – is irrelevant.

The Track 2 defendants agree with the Track1 defendants that the unrefuted evidence in the record establishes as a matter of law that no one believed that AWP represented actual acquisition costs or an actual "average" of prices in the same sense plaintiffs now urge, and that summary judgment dismissing the complaint should be granted for that reason, among others.

It is not our intention to interject the Track 2 defendants in briefing motions pending before the Court to which the Track 2 defendants are not party. We understand that the Track 2 defendants will be given a chance in the future to have its arguments heard. Nevertheless, to the extent the Court intends to give precedential effect to a definition fashioned in the course of deciding the current motions, the Track 2 defendants believe it essential to make clear that the Track 2 defendants do not agree that it is necessary or appropriate for the Court to construe the legal meaning of AWP in the Medicare statutes or regulations.

If the Court agrees, the Track 2 Defendants would be prepared within twenty days to file a memorandum addressing these issues. It does not appear that this would delay the Court's resolution of the pending motions.

Dated: June 12, 2006

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 12th day of June, 2006, a true and correct copy of the foregoing document was served upon all counsel of record by electronic service pursuant to CMO No. 2, by causing a copy to be sent to LexisNexis File & Serve for posting and notification to all counsel of record.

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s/ Philip D. Robben [signature on file]

Philip D. Robben